WOMEN'S INTERAGENCY HIV STUDY
CLINICAL OUTCOME REPORTING FORM

ID LABEL HERE ---> |__| - |__|__| - |__|__|__|__| - |__|

FORM COMPLETED BY: ___ ___ ___

VERSION DATE: 04/01/03

DATE OF THIS REPORT: ___ ___ / ___ ___ / ___ ___
M D Y

EVENT TRACKING NUMBER: ___ ___ ___ ___ ___ ___ ___ ___
(from ACS)

REASON FOR STATUS CHANGE (circle all that apply):

a. AIDS diagnosis . . . . . .
Complete sections A & B 1

b. Malignancy
Complete sections A & B 2

c. Tuberculosis
Complete sections A & B 3

d. Mortality
Complete sections A & C 4

e. Chronic disease (non-HIV) diagnosis
Complete sections A & B 5

NOTE: *If chronic disease diagnosis = hepatitis/liver disease (i.e., disease code = 320), also complete Section D of this form.*

WIHS ID #

SECTION A. SOURCE OF INFORMATION

A1. SOURCE OF INFORMATION – *Circle ONE source of information for this event. If there are multiple sources of information, complete additional CORE Forms.*

Medical Records:

a. Copy on file 1
b. Copy not on file/Abstracted 2

Death Certificate 4

Autopsy 5

Registry Sources:

a. AIDS Registry 6

Source: _____

b. Cancer Registry 7

Source: _____

c. TB Registry 8

Source: _____

d. Death Registry 9

Source: _____

Other Source 10

Source: _____

PROMPT: IF SOURCE OF INFORMATION IS REGISTRY MATCH (A1 = 6, 7, 8 OR 9), COMPLETE A2 BELOW. OTHERWISE, SKIP TO SECTION B.

A2. Registry Search Criteria (circle one):

Whole cohort 1
HIV+ 2
Medical release and self-report 3
Medical release only 4
Other 5

Specify: _____

WIHS ID #

SECTION B. CLINICAL DIAGNOSIS

Complete a separate CORE Form for each unique diagnosis.

B1. Date of Diagnosis *(If date of diagnosis is unknown, check the box to indicate it is missing.)*

___ ___ / ___ ___ / ___ ___ Missing ☐
M D Y

a. Name of diagnosing facility: _____

b. Address of diagnosing facility: _____

B2. Disease *(Print diagnosis.)* _____

a. If Disease (question B2) = metastatic cancer, to what body location has cancer metastasized? *(If Disease ≠ metastatic cancer, enter "-1" in question B2a.)* _____

B3. Disease Code *(See Manual of Operations, Section 12, for list of disease codes.)* _____ _____ _____

PROMPT: IF DISEASE CODE = 320 (HEPATITIS/LIVER DISEASE), COMPLETE SECTION D OF THIS FORM (DETAILED LIVER DISEASE ABSTRACTION ADDENDUM).

B4. Method(s) of Diagnosis *(Circle the code(s) for up to THREE methods of diagnosis.)*

Histology at biopsy	1
Necropsy	2
Cytology	3
Culture	4
Serology	5
Clinical Diagnosis	6
Radiology (MRI, imaging, etc.)	7
No confirmation/clinician report	8
Reported on death certificate	9
Unknown, other diagnosis	-9

B5. Confidence *("Indeterminate" should be circled if B4 = 8 or 9. See CORE Form QxQs.)*

Definitive	1
Presumptive	2
Indeterminate	3

WIHS ID #

SECTION C. INFORMATION RELEVANT TO DEATH

Complete all items in this section.

C1. Date of death *(If date of death is unknown, check the box to indicate it is missing.)*

___ ___ / ___ ___ / ___ ___ Missing ☐
M D Y

C2. Source of initial information about death *(Circle yes or no for each.)*

		YES	NO
a.	Report of family/friends	1	2
b.	Hospital	1	2
c.	Death certificate search	1	2
d.	Obituary notice	1	2
e.	Report from health care provider or social service provider	1	2
f.	AIDS surveillance	1	2
g.	Other source	1	2

Specify: _____

C3. Place of Death *(Circle one.)*

Hospital (Inpatient) 1
ER/Outpatient 2
Nursing Home 3
Hospice/Extended Care Facility 4
Residence 5
Other location 6

Specify: _____

C4. Location of Death

a. County: _____ b. City: _____

c. State: _____ d. Country: _____

C5. Manner of Death *(Circle one.)*

Natural 1
Accident 2
Suicide 3
Homicide 4
Pending investigation 5
Could not be determined 6
Not stated on certificate 7

WIHS ID #

C6. Causes of death *(If causes of death are unknown, list as "unknown.")*

	Condition *(print diagnosis)*
Immediate Cause:	_____
Underlying Cause(s):	(a)_____
	(b)_____
	(c)_____
	(d)_____
	(e)_____
	(f)_____
	(g)_____
Other Significant Conditions:	(a)_____
	(b)_____
	(c)_____
	(d)_____
	(e)_____
	(f)_____
	(g)_____

C7. Autopsy performed:

Yes 1
No 2
Don't know . . . . . -8

WIHS ID #

SECTION D. DETAILED LIVER ABSTRACTION ADDENDUM

PROMPT: COMPLETE THIS ADDENDUM ONLY IF THE RESPONSE TO QUESTION B3 = 320 (HEPATITIS/LIVER DISEASE).

D1. Is there serologic evidence of a new Hepatitis C virus infection?

Yes 1
No 2

D2. Is there a clinical diagnosis of an acute, symptomatic Hepatitis C syndrome?

Yes 1
No 2

D3. Is there a clinical diagnosis of cirrhosis?

Yes 1
No 2

D4. Is there a clinical diagnosis of other liver disease?

Yes 1
No . . . . . 2 **(PROMPT)**

a. SPECIFY: _____

PROMPT: IF ALL OF QUESTIONS D1–D4 = NO, SKIP TO END OF FORM. OTHERWISE, IF ANY OF D1–D4 = YES, PROCEED TO QUESTION D5.

D5. In the notes referring to any of the above diagnoses is there mention of:

		YES	NO
a.	Nausea and/or vomiting	1	2
b.	Abdominal pain	1	2
c.	Decreased appetite	1	2
d.	Fever	1	2
e.	Myalgia (muscle aches)	1	2
f.	Pruritus (itching)	1	2
g.	Weight loss	1	2
h.	Malaise	1	2
i.	Jaundice (yellow skin/eyes)	1	2

WIHS ID #

		YES	NO
j.	Enlarged liver	1	2
k.	Ascites (fluid in the belly)	1	2
l.	Spider angiomatas (on skin)	1	2
m.	Hepatic endephalopathy: altered mental status (AMS), coma, asterixis (flapping tremor)	1	2
n.	Varicies noted on endoscopy	1	2
o.	Increased serum ammonia	1	2
p.	Increased transaminases ALT (SGPT), AST (SCOT), GGT	1	2
q.	Increased bilirubin and alkaline phosphatase	1	2
r.	Decreased albumin	1	2
s.	Prolonged PT/PTT	1	2
t.	Liver biopsy (abstract pathology report)	1	2
u.	Treatment: ribiviron, interferon alpha, Rebetron (combination)	1	2